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SPECIAL MASTER LETTER ORDER

April 7, 2025

VIA ECF and Email
TO ALL COUNSEL OF RECORD

RE: ***Johnson & Johnson Health Care Systems, Inc. v. SaveOnSP, LLC***
Civ. Action No.: 22-2632(CCC)(CLW)

Counsel:

On April 1, 2025, I held oral argument on the following three discovery motions filed by Defendant SaveOnSP, LLC ("SaveOnSP" or "Defendant"): 1) motion to add Lena Kane as a custodian; 2) motion to compel PAFA+ documents; and 3) motion to compel Plaintiff Johnson & Johnson Health Care Systems, Inc. ("Plaintiff" or "JJHCS") to run advocacy group-related search terms over three existing custodians, as well as two motions filed by Plaintiff: 1) motion to compel responses to Interrogatory No. 22; and 2) motion to compel Defendants Accredo Health Group, Inc. ("Accredo") and Express Scripts, Inc. ("Express Scripts") to produce documents without certain redactions. This Letter Order memorializes, and expands upon, the rulings I made on the record in connection with these motions.

I. Motion to Add Lena Kane as a Custodian

In this motion, Defendant seeks to compel Plaintiff to designate Lena Kane as a custodian and to apply targeted search terms to her files concerning J&J's compliance with the Best Price Rule. This issue has been addressed twice before. First, in May 2024,

Defendant requested documents related to Plaintiff's "best price" certification to the federal government under the Department of Health and Human Services' Best Price Rule. The Best Price Rule is a federal regulatory framework requiring drug manufacturers to ensure that Medicaid recipients receive the lowest available market price for prescription medications. Pursuant to this rule, manufacturers must submit quarterly reports to the government detailing various pricing data in accordance with federal guidelines. *See* 42 C.F.R. § 447.510(a). Drug manufacturers may exclude copay assistance from the Best Price calculation, provided the assistance is intended to benefit patients directly.

Defendant asserted that it is entitled to Best Price-related documents in support of its mitigation defense—specifically, to demonstrate that Plaintiff modified certain terms and conditions of its CarePath program and created the CAP Program in response to the 2023 Best Price Rule,[1] which ultimately never went into effect. While acknowledging that such documents might shed light on Plaintiff's intent and motivation in identifying patients participating in SaveOnSP's programs, I directed Defendant to first serve interrogatories on Plaintiff. These interrogatories were to explore the purpose of an internal checklist that may—or may not—relate to Plaintiff's obligations under the Best Price Rule. This checklist, created by J&J for new, renewed, or amended copay assistance programs, instructed employees to confirm, among other things, that "the full value of

[1] In 2020, the Department of Health and Human Services proposed amending the Best Price Rule to require manufacturers to include copay assistance payments in Best Price calculations, unless the full benefit of those payments was passed on to the patient.

the assistance is passed on to the consumer." In addition, Defendant was directed to inquire into who was responsible for creating the checklist. I emphasized that the interrogatories must be narrowly tailored and specifically targeted.

After Defendant served Plaintiff with three interrogatories regarding the internal checklist in December 2024, Defendant moved to compel Plaintiff to answer certain portions of those interrogatories. Interrogatory 12 asked the following:

> Describe the purpose and meaning of the Savings Program Checklists, including the meaning of the statements like those highlighted in Appendix 1; what steps, if any JJHCS took to ensure that these statements were accurate; when and why JJHCS created the Savings Program Checklists and, if applicable, stopped using them; and how the Savings Program Checklists relate to calculations or submissions of best price information pursuant to 42 C.F.R. § 447.505.

Plaintiff responded as follows:

> The "Coupon and Free Product" checklist was an internal means of tracking whether new or modified patient assistance programs, including CarePath's co-pay assistance programs, had undergone internal compliance review before being made available to the public. Johnson & Johnson attorneys and compliance specialists generally reviewed internal drafts of the "Coupon and Free Product" checklists for accuracy and to confirm that new or modified patient assistance programs complied with Johnson & Johnson's legal obligations. In so doing, Johnson & Johnson also confirmed that its patient assistance programs complied with Johnson & Johnson's obligations under the Medicaid Drug Rebate Program. The "Coupon and Free Product" checklists were not submitted to the government and did not otherwise relate to Johnson & Johnson's "calculations or submissions of best price information pursuant to 42 C.F.R. § 447.505." The "Coupon and Free Product" checklists were created prior to the Time Period and continued to be used after the Time Period.
>
> The purpose of the language in Part III, Sections 3 and 8 of the internal "Coupon and Free Product" checklist (JJHCS_00204199) is meant to ensure these patient assistance programs, including CarePath's co-pay assistance program, operate consistently with Johnson & Johnson's compliance goals.

> The language in Part III, Sections 3 and 8 of JJHCS_00204199 predate the Time Period and remained in effect after the Time Period.

During motion practice, Plaintiff further clarified—and later incorporated this clarification into its interrogatory response—that the checklist process was intended to confirm that its patient assistance programs complied with J&J's obligations under the Medicaid Drug Rebate Program, which necessarily includes compliance with the Best Price Rule. Plaintiff emphasized that the checklist items were not created in response to, nor were they otherwise connected to, the proposed amendment to the Best Price Rule. I denied Defendant's motion to compel, finding that Plaintiff's responses were sufficient and that any remaining questions could be addressed during depositions.

Plaintiff's interrogatory response identified two employees in its Government Contract Compliance Group (the "GCC") with responsibility for reviewing the relevant portions of its Savings Program Checklists, one of whom was Lena Kane, the Director of J&J's GCC group, with primary responsibility for ensuring that sales of drugs to federal health plans comply with the Best Price Rule. Plaintiff refused to add Kane as a custodian and this motion ensued.

Defendant contends that Kane likely possesses unique, relevant documents concerning how J&J developed its efforts to identify patients and why those efforts did not begin until the 2023 Best Price Rule was proposed. Beyond the scope of the Best Price Rule, Defendant also asserts that Kane is likely to have documents related to: (1) J&J's provision of CarePath funds and its interpretation of the May-Not-Use Provision; (2) J&J's evolving incentives to identify patients enrolled in SaveOn-advised plans; (3) the CAP

program; and (4) CAP 2023. In connection with these categories, Defendant seeks to apply 11 search terms to Kane's documents over a period of nearly two years.

As already determined, under the current language of the Best Price Rule, Plaintiff is not required to treat CarePath assistance payments as discounts, provided the assistance is passed directly to patients. SaveOnSP's alleged scheme—namely, the indirect diversion of CarePath funds to insurance plans as a cost-saving mechanism—does not implicate the Best Price Rule. The Rule is designed to ensure that the full value of such assistance is received by the consumer or patient. There is no allegation by Defendant, Plaintiff, or in the Complaint that CarePath funds are paid directly to insurance plans or to Defendant in a manner that would trigger the application of the Rule.

Setting aside the Rule's applicability, Defendant has not demonstrated how any of Plaintiff's compliance documents are relevant to its defenses. This is precisely why Defendant was permitted discovery only into the internal checklist—to determine whether its creation informs Plaintiff's decision to revise CarePath terms in 2022 and to implement the CAP program—in support of Defendant's mitigation defense. Plaintiff has already addressed this issue in interrogatory responses, and Defendant will have the opportunity to question witnesses during depositions on this limited topic.

Nevertheless, dissatisfied with the responses, Defendant now seeks to apply 11 broad search terms to Kane's files. To the extent these terms relate to the Best Price Rule, Kane shall not be added as a custodian. Given the limited relevance of that issue and the discovery already provided, further collection from Kane is not proportional to the needs

of the case. As for the remaining proposed terms, Kane is still not an appropriate custodian. Based on the exhibits submitted by Defendant that I have reviewed, there are already numerous custodians covering these topics. Kane, who served as a director in the Government Contract Compliance Group, is unlikely to possess unique, non-cumulative documents central to this case. As such, Defendant's motion is denied.

II. Motion to Compel SaveOnSP to Supplement Its Response to Interrogatory No. 22

Plaintiff moves to compel SaveOnSP to answer JJHCS's Interrogatory No. 22 and provide, *inter alia*, compensation and bonus information as to Ayesha Zulqarnain, Alissa Langley, Kelsey Leger, and Jessica Johnson. JJHCS previously sought the personnel files of four SaveOnSP employees to assess whether SaveOnSP encouraged and rewarded employees alleged deceptive conduct. I denied Plaintiff's motion; after an *in camera* review, I found that personnel files contain information that is both private and irrelevant to the case. However, JJHCS was permitted to serve only one additional interrogatory seeking compensation and bonus information regarding the four specific employees.

Pursuant to that directive, Plaintiff served Interrogatory No. 22, which asks SaveOnSP to identify for each of the four employees, for each year during the relevant time period: (i) annual salary; (ii) year-over-year compensation increases; (iii) bonuses; (iv) incentive awards; (v) any other forms of pay or incentives; and (vi) the basis used by SaveOnSP to determine each of these awards, including any feedback, supervisor comments, praise, evaluations, or other performance metrics.

SaveOnSP objected on relevance and burden grounds, and responded that the employees' compensation—including salary, bonuses, or other incentives—was never impacted or changed as a result of any alleged efforts to deceive pharmaceutical manufacturers. Plaintiff challenges this response, arguing that SaveOnSP should provide the requested compensation and bonus information. Plaintiff asserts that the question of whether SaveOnSP leadership used financial incentives to encourage employees to engage in unlawful conduct is one for the jury, not Defendant, and that SaveOnSP has yet to provide the factual information needed for JJHCS to make its case.

In response, SaveOnSP contends that Plaintiff's interrogatory seeks comprehensive compensation details and all bases for that compensation, including employee evaluations, rather than limiting its request to compensation tied to alleged misconduct. SaveOnSP states that it investigated and determined that the employees' compensation was not affected by any purported evasive conduct, and responded to the interrogatory accordingly. However, it did not produce any compensation or bonus data.

Defendant is correct that, apart from compensation and bonus details, Plaintiff's Interrogatory No. 22 seeks substantially similar categories of information previously requested from the employees' personnel files—specifically, salary, compensation increases, bonuses, incentive awards, feedback, supervisor comments, statements of praise, and evaluations. In my prior ruling, I confirmed that SaveOnSP's representations were accurate and held that no further production from the personnel files would reveal any indication that SaveOnSP commented on, or rewarded, employee actions concerning manufacturers' terms and conditions or the administration of the SaveOnSP program.

Accordingly, Plaintiff is not permitted to seek information beyond the limited scope previously authorized.

Nonetheless, even with respect to compensation and bonus information, Defendant argues that Plaintiff is not entitled to this discovery absent a demonstrable link between the employees' compensation and the alleged deceptive conduct. Defendant maintains that without such a link, the requested information lacks relevance and should be protected. As courts have consistently held, a party seeking sensitive information from personnel files must make a clear showing of relevance. Here, Defendant contends that Plaintiff offers no such evidence—only speculation—and emphasizes that I have already found no indication that SaveOnSP commended or rewarded the employees for allegedly evasive conduct.

However, that finding is only limited to the personnel files. There may be verbal or other written communications that would reveal a link between compensation and certain employees' conduct. This is precisely the reason that I permitted Plaintiff to serve an interrogatory to inquire solely about the four employees' compensation and bonus. Indeed, Plaintiff may use compensation-related facts at trial, provided there is sufficient supporting evidence in the record. During discovery, Plaintiff is entitled to test Defendant's representation that the employees' alleged conduct had no bearing on their compensation. While the personnel files may not contain such information, Plaintiff may explore this issue through deposition testimony. If discovery reveals a factual basis, Plaintiff may argue at trial that raises or bonuses were tied to the alleged misrepresentations made to advance SaveOnSP's scheme. Of course, Defendant remains

free to file a motion *in limine* to exclude such evidence or to challenge it before the jury. For now, however, Plaintiff is entitled to obtain compensation and bonus information for the four employees, consistent with my prior ruling. Accordingly, Plaintiff's motion is granted in part and denied in part.

III. Motion to Run Search Terms over Existing Custodians Related to Advocacy Groups

Defendant moves to compel Plaintiff to run a limited set of search terms over the documents of existing custodians 1) John Hoffman, 2) Lawrence Platt, and 3) Silas Martin regarding J&J's work with patient advocacy groups (RFP No. 77) and pharmaceutical industry associations (RFP No. 78) related to public statements, patient outreach, and lobbying about copay assistance programs, maximizers, accumulators, or SaveOnSP.[2]

Defendant seeks these documents for two reasons: First, Defendant argues that documents about J&J's work with Advocacy Groups are relevant because they speak to the credibility of the Advocacy Groups, which J&J put at issue by relying on them in this litigation. Second, Defendant submits that documents will likely show that, through its work with the Advocacy Groups, Plaintiff itself caused patients the "stress and confusion" for which it seeks to hold SaveOn liable in its General Business Law ("GBL") claim.

A. Advocacy Groups' Credibility

Defendant argues that it is entitled to the documents covered by the RFPs at issue, because JJHCS has either directly relied on or received support from various advocacy

[2] I will refer to advocacy groups and pharmaceutical industry associations collectively as "Advocacy Groups."

groups in this litigation. Specifically, Defendant contends that, since Plaintiff has cited the work of certain advocacy groups in its pleadings and since others filed amicus briefs in support of Plaintiff at the motion to dismiss stage, any intention by Plaintiff to introduce evidence or testimony from these groups places their credibility at issue. Defendant maintains that it is therefore entitled to discovery showing that Plaintiff allegedly paid for and influenced the advocacy groups' positions against accumulator and maximizer programs, as well as against SaveOnSP.

On the other hand, Plaintiff argues that whether it provides financial support to patient advocacy groups critical of maximizer programs is irrelevant to the claims or defenses in this case. Plaintiff contends that Defendant has failed to establish any link between such support and any element of Plaintiff's claims or Defendant's defenses. Plaintiff further notes that Defendant has already received substantial discovery on these issues, including documents showing JJHCS's grants to certain advocacy organizations related to their work on issues implicated in this litigation.

Nevertheless, Defendant asserts that its discovery requests are not directed at claims or defenses per se, but rather seek evidence of potential bias. Defendant argues that JJHCS did not merely fund these advocacy groups but collaborated with them to shape and promote narratives that align with J&J's corporate interests and that it then cited these narratives in support of its claims. Contrary to Plaintiff's position, Defendant argues that it is entitled to probe whether Plaintiff's support influenced the positions taken by these groups, especially if Plaintiff intends to rely on testimony or written materials authored by individuals affiliated with or financially supported by Plaintiff.

Notably, during oral argument, Plaintiff's counsel did not deny that Plaintiff may introduce testimony or documentary evidence from these Advocacy Groups at trial. Indeed, Plaintiff has cited materials from advocacy groups in its pleadings. For example, the Amended Complaint references work by the Association of Community Cancer Centers (ACCC), the Arthritis Foundation, and litigation brought by the Households for Health Policy Initiative (HHPI). *See* Am. Compl. ¶¶ 30 n.6, 32 & n.9, 50. In addition, several of these groups appeared as amici curiae in this case, supporting Plaintiff's position. *See* Dkt. 35 (motion for leave to appear as amicus curiae by Aimed Alliance, HHPI, CSRO, and the AIDS Institute); Dkt. 38 (PhRMA's motion for leave to appear as amicus curiae).

Hence, I find that this line of inquiry is a legitimate basis for discovery. Courts have long recognized that bias is a proper subject for impeachment and that discovery into potential bias is appropriate where a party intends to rely on testimony from potentially interested witnesses. *See, e.g.*, *Hughes v. Long*, 242 F.3d 121, 130 (3d Cir. 2001) (holding that discovery into a witness's potential bias is relevant and permissible). As to search terms, the parties are directed to confer on a narrow and targeted set of terms related to the Advocacy Groups' credibility, which may include funding or financial assistance related terms, to run over the four employees at issue.

B. Stress and Confusion

In its GBL claim, Plaintiff alleges that Defendant's program harms the public—including patients—by causing undue stress and confusion. Defendant counters that it is Plaintiff, not SaveOnSP, who is actually responsible for the stress and confusion alleged.

In support, Defendant references Plaintiff's media strategy, developed in coordination with its public relations consultant Rational360, which, according to Defendant, was intentionally designed to keep J&J in the background while allowing advocacy groups and coalitions to take the public lead in opposing accumulator and maximizer programs. Defendant argues that this behind-the-scenes approach was intended to mask Plaintiff's own interests and avoid appearing self-serving.

Defendant argues that this approach reflects a deliberate effort by Plaintiff to publicly discredit programs like SaveOnSP through third-party advocacy, while shielding J&J from direct scrutiny. As a result, Defendant contends that it is entitled to discovery to show that Plaintiff—through its coordination with advocacy groups and vendors—was the true source of the stress and confusion alleged in the Complaint. This theory rests on several alleged facts:

1. Plaintiff worked with advocacy groups it financially supported and with Rational360 to disseminate messaging that accused programs like SaveOnSP's of negatively affecting patients' access to and affordability of medications.

2. Plaintiff sought to rally patient engagement in hopes of influencing employers, policymakers, and advocacy organizations to take action against programs like SaveOnSP.

3. Defendant highlights the story of Anndi McAfee, a patient whose article describing a negative experience with SaveOnSP was cited in the Complaint. In the article, McAfee described the burden she faced navigating her insurance coverage and accessing medication. However, Defendant maintains that McAfee first learned about SaveOnSP through TrialCard, which inaccurately led her to believe that her medication had been downgraded in importance. TrialCard then introduced her to an advocacy group, and a few days later, she published the article. Defendant argues that McAfee had not reported any distress while actually

> participating in SaveOnSP's program and that her negative experience only arose after interacting with Plaintiff's vendor and advocacy network.

Based on these assertions, Defendant submits that it should be permitted discovery to test its theory that Plaintiff orchestrated the narratives of patient distress and confusion now central to its GBL claim. This, Defendant contends, is directly relevant to its defense.

As a general matter, I do not find Defendant's argument persuasive. It has not presented any credible evidence suggesting that the discovery it seeks would lead to admissible evidence. To begin, there is nothing inherently improper about Plaintiff advocating against SaveOnSP and similar entities, or engaging with advocacy groups, patients, and policymakers to oppose accumulator and maximizer programs. Plaintiff had clear business reasons for such efforts. However, vigorous advocacy alone does not establish that Plaintiff caused stress or confusion among patients. None of the materials cited by Defendant support the conclusion that Plaintiff's actions were the source of any patient distress.

More fundamentally, the discovery Defendant seeks is not particularly relevant. Defendant argues that any stress or confusion allegedly caused by JJHCS through its advocacy efforts would undermine Plaintiff's GBL § 349 claim by offering an alternative source of harm. But even assuming, arguendo, Plaintiff's conduct did cause some patient confusion or stress, that does not negate the type of harm that Plaintiff must prove for its claim under the statute.

To prevail on a GBL § 349 claim, Plaintiff must show that SaveOnSP's conduct caused harm to the public at large. JJHCS has alleged that SaveOnSP's program causes

such harm by generating undue stress and confusion, including through false denials of coverage, delays in medication access, and increased out-of-pocket costs due to manufacturer assistance not counting toward patients' ACA out-of-pocket maximums or deductibles. Defendant cannot avoid its own liability by pointing to conduct by Plaintiff that allegedly caused similar harm.[3]

That said, during oral argument, I permitted Defendant to explore a limited inquiry regarding direct contact that Advocacy Groups may have with CarePath patients. Should discovery reveal that these Advocacy Groups actually caused confusion amongst these patients who otherwise were satisfied with the SaveOnSP plan, I would consider permitting Defendant to further explore this topic. Because this is a limited inquiry—not the broader inquiry that Defendant seeks on this motion—the parties must confer on limited search terms and appropriate custodians. While I am not weighing in on this process, I stress, at the outset, that the number of search terms and custodians must be limited. This ruling does not intend to open discovery into the harm and stress that Defendant seeks on this motion. Accordingly, Defendant's motion is granted in part and denied in part.

IV. Motion to Compel PAFA+ Documents

On this motion, Defendant moves to compel Plaintiff to produce documents sufficient to show which individuals at J&J had access to PAFA+ -- its centralized

[3] Defendant has not brought any affirmative claims against Plaintiff that would make such discovery relevant to any counterclaim or defense.

database of information about individuals enrolled in CarePath -- so that the parties can negotiate an appropriate custodian with access to this information. Alternatively, Defendant requests that J&J add as a custodian the most senior person at J&J with access to PAFA+.

SaveOn also moves to compel three categories of data contained in PAFA+: (1) all records related to Benefits Investigations that determine whether a patient was on an accumulator, maximizer, or SaveOn-advised plan; (2) all case-and-task notes for patients that J&J or any of its vendors identified as on an accumulator, maximizer, or SaveOn-advised plan; and (3) all Patient Segmentation Decisions for all drugs at issue in this litigation.

PAFA+ is a database of CarePath patient information—maintained by third party vendors, such as TrialCard and RIS RX. Based on the screenshots of the PAFA+ database, it appears the database contains, at least, the following information:

1. Information that identifies the patient;

2. Actions taken by Plaintiff to determine whether the patient was enrolled in an accumulator or maximizer program, including whether a benefits investigation (BI) was conducted;

3. Records of communications related to the BI, including any correspondence from Plaintiff to the patient upon discovering the patient was in an accumulator or maximizer program; and

4. Any changes Plaintiff made to the patient's enrollment status, including whether the patient was transferred into the CarePath program variations designed for accumulator and maximizer patients—CAPa and CAPm.

Additionally, it appears that the database contains various records, such as Benefits Investigations ("BIs") conducted by vendors, case-and-task notes (containing the

history of actions, such as phone calls and letter sent, on each patient's account, and Patient Segmentation Decisions ("PSDs"), which involve transferring a patient to a particular CAP program, *i.e.*, CAPa or CAPm.

A. Identification of J&J Employees

Defendant represents that it has been seeking information contained in the PAFA+ database for years. According to Defendant, Plaintiff initially stated that no database existed that could identify patients enrolled in accumulator programs, maximizer programs, or SaveOn-advised plans. However, when confronted with the existence of the PAFA+ database in June 2024, Plaintiff refused to produce the requested materials. Defendant argues that the information in PAFA+ is necessary to understand the full scope of Plaintiff's mitigation efforts on a patient-by-patient basis. Additionally, although Plaintiff has acknowledged that some J&J employees had access to patient information within PAFA+, it has declined to identify those individuals. Defendant contends that documents related to PAFA+ are relevant to its mitigation defense because they may show which J&J employees had access to the data and, accordingly, who knew or should have known which patients were enrolled in accumulator, maximizer, or SaveOn-advised plans.

Plaintiff responds that the identity of JJHCS employees with access to PAFA+ is irrelevant. In Plaintiff's view, the key issue in relation to Defendant's failure-to-mitigate defense is whether the database was sufficiently complete, accurate, and reliable to justify further action by JJHCS. Plaintiff maintains that SaveOnSP can make its arguments at trial, including any claim that JJHCS should have done more to respond to patient

enrollment in SaveOnSP despite the risk to patient health and SaveOnSP's allegedly deceptive efforts to obscure such enrollment. Plaintiff also argues that it is not claiming JJHCS failed to act due to lack of access to PAFA+, and thus compiling a list of users with access is neither feasible nor proportional to the needs of the case.

Plaintiff's position is unconvincing. Defendant correctly asserts that evidence showing which J&J employees had access to patient information in PAFA+ may support its argument that J&J knowingly continued to provide copay assistance despite awareness of SaveOnSP's conduct, thereby failing to mitigate damages. Discovery into Plaintiff's knowledge—particularly the identities of individuals with access to relevant data—is directly relevant to this defense and may reveal whether a J&J decisionmaker acted inconsistently with Plaintiff's litigation position. Moreover, Plaintiff has not shown that identifying these employees would impose an undue burden. To be clear, Defendant is not presently requesting that a custodian be designated for production purposes; the identification of a custodian is sought only as an alternative form of relief. As such, Plaintiff shall produce a list of J&J employees who had access, whether view only access or otherwise, to the PAFA+ database. In terms of time period, I directed the parties to confer on this issue. While I am not making a finding, the period of December 2021 to November 2023 appears to be adequate.

B. Three Categories of Data[4]

With respect to data, Defendant seeks: (1) benefits investigation (BI) information for patients taking medications beyond Stelara and Tremfya, including the oncology drug Erleada and the pulmonary arterial hypertension (PAH) drugs Opsumit, Uptravi, and Tracleer; (2) case-and-task notes; and (3) patient segmentation decisions. During oral argument, Plaintiff made various representations regarding its production of these categories of data—both from the PAFA+ database and other sources—through custodian and non-custodial searches. According to Plaintiff, much of the information Defendant seeks has already been produced.

There appears, however, to be some confusion regarding the scope of the production and whether it fully addresses the categories of data sought by Defendant. In light of this, I directed Plaintiff to provide written correspondence to Defendant outlining, with specificity, what has been produced to date that would correspond to the requested data categories. To be clear, I am not making any determination at this time as to whether Defendant is entitled to all the data it seeks—whether from PAFA+ or any other source.[5] Rather, my directive is limited to having Plaintiff clarify its existing

[4] Defendant also seeks missing fields in RIS Rx production. Defendant argues that RIS Rx has not reliably produced all records related to BIs that it performed. While Plaintiff recently produced internal documents showing that RIS Rx collected 24 data fields for every BI, the spreadsheet that Plaintiff produced of RIS Rx's files contains only ten data fields. Plaintiff represents that it will investigate whether any such additional fields exist.

[5] I also permitted Defendant to serve one limited interrogatory, with no subparts, that inquires whether there are other sources of data, besides PAFA+, and the names of those sources that contain the relevant categories of data.

production so that Defendant can meaningfully assess what, if any, additional data it intends to pursue through PAFA+ sought in this motion that has not yet been produced. The parties may further meet and confer regarding any outstanding discovery. If issues remain following that process, Defendant may submit a letter for my consideration.

V. Motion to Compel Production without CHI Redactions

Plaintiff moves to compel Defendants Accredo and Express Scripts (collectively, "Defendants") to produce documents without redacting confidential health information ("CHI"), consistent with the Discovery Confidentiality Order ("Protective Order") entered by the Court. Defendants oppose the motion, arguing that Plaintiff is seeking unrestricted access to thousands of patients' Protected Health Information ("PHI"), which they contend is a more narrowly defined and highly sensitive category of data entitled to heightened protection under the Health Insurance Portability and Accountability Act ("HIPAA"). According to Defendants, in order to comply with both the Protective Order and HIPAA, Plaintiff must first identify the specific confidential information it seeks, thereby enabling Defendants to produce documents in a manner consistent with HIPAA's privacy requirements. I disagree.

A. HIPAA Statutory Framework

To resolve this dispute, I start with HIPAA's framework. There is no doubt that HIPAA places strict limitations on the ability of health care providers to release a patient's medical records or discuss the patient's medical history without the consent of the patient. *See South Carolina Med. Assoc. v. Thompson*, 327 F.3d 346, 348 (4th Cir. 2003).

HIPAA's privacy rules set forth standards and procedures for the collection and disclosure of "protected health information." The information includes:

> [any information, whether oral or recorded in any form or medium, that]:
>
> (1) [i]s created or received by a health care provider, health plan, employer, or health care clearinghouse; and
>
> (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and
>
> (i) That identifies the individual; or
>
> (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

45 C.F.R. § 160.103 (defining "individually identifiable health information," which generally encompasses "protected health information").

Indeed, HIPAA prohibits "covered entities," such as Defendants here, from using and disclosing private health information as required or permitted by the relevant regulations. Importantly, the privacy rules prohibit covered entities, including health care providers, from using or disclosing private health information in any form oral, written or electronic, except as permitted under the rules. 45 C.F.R. § 164.502(a). However, relevant here, the regulations provide certain exceptions to the general rule against disclosure of patient health information without the patients' prior written consent.

One such exception relates to the disclosures made in connection with judicial and administrative proceedings. *See* 45 C.F.R. § 164.502(a)(1)(vi)(B); § 164.512(e) (titled "Uses and disclosures for which an authorization or opportunity to agree or object is not

required."). Health care providers may disclose protected health information within judicial and administrative proceedings according to the following guidelines:

> (1) Permitted disclosures. A covered entity may disclose ***protected health information*** in the course of any judicial or administrative proceeding:
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> (i) In response to an order of a court or administrative tribunal, provided that the covered entity discloses only the protected health information expressly authorized by such order; or
>
> (ii) In response to a subpoena, discovery request, or other lawful process, that is not accompanied by an order of a court or administrative tribunal, if
>
> > (A) The covered entity receives satisfactory assurance . . . from the party seeking the information that reasonable efforts have been made by such party to ensure that the individual who is the subject of the protected health information that has been requested has been given notice of the request; or
> >
> > (B) The covered entity receives satisfactory assurance . . . from the party seeking the information that reasonable efforts have been made by such party to secure ***a qualified protective order*** that meets the requirements of paragraph (e)(1)(v) of this section.

45 C.F.R. § 164.512(e)(1) (emphasis added).

A qualified protective order, such as the one in this case, must both prohibit the parties from using or disclosing the patient's health information for any purpose not related to the judicial proceeding in which its production was ordered and require that the parties return or destroy the disclosed information (as well as all copies made thereof) at the end of the proceedings. 45 C.F.R. § 164.512(e)(1)(v).

In short, HIPAA allows health care providers to disclose patient health information in connection with judicial proceedings: (1) in response to an order of the court, but only to the extent allowed by the language of the order; or (2) in response to a

subpoena or formal discovery request where the requesting party assures the provider that either the patient was made aware of the request but did not object or the requesting party has made reasonable efforts to secure a proper protective order. *Wade v. Vabnick-Wener*, 922 F. Supp. 2d 679, 687 (W.D. Tenn. 2010); *Law v. Zuckerman*, 307 F. Supp. 2d 705, 711 (D. Md. 2004); *EEOC v. Boston Mkt. Corp.*, No. 03-4227, 2004 U.S. Dist. LEXIS 27338, at *7 (E.D.N.Y. Dec. 16, 2004); *Nat'l Abortion Fed'n v. Ashcroft*, No. 03-8695, 2004 U.S. Dist. LEXIS 4530, at *7 (S.D.N.Y. Mar. 19, 2004); *see also* 45 C.F.R. § 164.512(e)(1)(i), (ii).

As an initial matter, Defendants object to Plaintiff's use of the term "Confidential Health Information," as defined in the Protective Order, and argue—without citation to legal authority—that "Protected Health Information" is a more narrowly defined category entitled to heightened protection under HIPAA. However, the Protective Order expressly defines CHI to include PHI as outlined by HIPAA, encompassing medical bills, claims forms, charge sheets, medical records, itemized billing statements, and any notes, summaries, or other materials derived from such information. (Protective Order ¶ 3(a).) More importantly, HIPAA expressly permits the disclosure of PHI in the course of judicial or administrative proceedings. *See* 45 C.F.R. § 164.512(e)(1) ("Permitted disclosures. A covered entity may disclose ***protected health information*** in the course of any judicial or administrative proceeding." (emphasis added)). Accordingly, the distinction Defendants attempt to draw between CHI and PHI is illusory. So long as the Protective Order satisfies HIPAA's requirements—which it does here—it governs the disclosure of confidential patient health information in this litigation.

Defendants further argue that Plaintiff seeks "unfettered access" to patients' health records. This characterization is incorrect. Plaintiff seeks only the information permitted under the Protective Order, which expressly provides that the parties shall produce discovery materials containing CHI—including PHI—in response to discovery requests without redaction. (Protective Order ¶ 3(c).) Defendants do not dispute that the specific information Plaintiff seeks to obtain unredacted falls within the scope of CHI as contemplated by the Protective Order.

Instead, Defendants contend that they are obligated to limit the disclosure of PHI to the "minimum necessary" to accomplish the intended purpose, relying on 45 C.F.R. § 164.502(b). They contend that, absent a more specific court order or a particularized justification from Plaintiff, they are prohibited from producing unredacted documents. However, Defendants cite no authority to support the applicability of the "minimum necessary" standard in the context of court-ordered discovery governed by a protective order. Moreover, the plain language of the HIPAA regulations directly undercuts Defendants' position.

Under 45 C.F.R. § 164.502(b)(2)(v), "minimum necessary" standard does ***not*** apply to "[u]ses or disclosures that are ***required by law***, as described by § 164.512(a) [(emphasis added)]." In turn, "required by law" means "a mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law. Required by law includes, but is not limited to, ***court orders*** and court-ordered warrants[.]" 45 CFR § 164.103 (emphasis added). Moreover, § 164.512(a) states that "[a] covered entity may use or disclose protected health information to the extent

that such use and disclosure is required by law and the use of disclosure complies with and is limited to the relevant requirements of such law . . . described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law." 45 CFR §§ 164.512(a)(1), (2). Subsection (e), of course, speaks to HIPAA's exception to nondisclosure in judicial proceedings with a qualified protective order executed by the court, as set forth above. Simply put, the "minimum necessary" standard does not apply in a judicial proceeding.

Based on this clear language, it is no surprise that courts have held that the "minimum necessary" requirement does not apply when a valid protective order is in place. *See Claims v. Sanofi-Aventis U.S. LLC*, No. 18-2211, 2023 U.S. Dist. LEXIS 124869, at *13 (D.N.J. July 14, 2023) (holding that the "minimum necessary" standard does not apply where a qualified protective order exists); *Jackson v. Wexford Health Sources, Inc.*, No. 20-900, 2022 U.S. Dist. LEXIS 152507, at *16 n.4 (S.D. Ill. Aug. 24, 2022) (same).

Even if the "minimum necessary" rule were applicable, Plaintiff has provided a legitimate basis for seeking the unredacted CHI. Plaintiff argues, which I find persuasive, that this information is critical to reviewing and cross-referencing patient-level data across Defendants' productions—specifically, to evaluate patient hardship resulting from the SaveOnSP program, assess Defendants' responses to patient complaints, and understand the nature of Defendants' interference with CarePath copay assistance. Requiring Plaintiff to justify the production of each document individually would run contrary to the terms of the Protective Order, which already limits the use of CHI to this litigation, restricts access to individuals bound by the Order, and mandates the return or

destruction of all CHI following the conclusion of the case. These safeguards are consistent with HIPAA's requirements.

Accordingly, under the terms of the Protective Order and applicable law, Defendants are required to produce unredacted CHI documents to Plaintiff's discovery requests. Plaintiff's motion is granted.

/s/ Freda L. Wolfson
Hon. Freda L. Wolfson (ret.)
Special Master